



HMA/EMA multi-stakeholder workshop on shortages

1-2 March 2023, EMA, Amsterdam

Communication and transparency: the Healthcare Professionals' perspective

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Shortages occur on a regular basis

INEXPENSIVE CANCER MEDICINES



Inexpensive essential medicines are **INDISPENSABLE** to treat and sometimes cure all types of cancer



All patients with cancer need some of these agents



About 80% of WHO Essential Cancer Medicines are inexpensive medicines (and as such subject at risk of shortage)



Availability of essential medicines is uneven among countries

ROMANIA

Table 1. Examples of cancer medicines affected by shortages in 2017 - 2018

Name of cancer medicine	Indication
Asparaginase	Acute lymphoblastic leukaemia
BCG (Calgevax)	Early stage bladder cancer
Calcium Folate	Administered to diminish the harmful effects of certain medicines and chemotherapeutic agents
Carmustine	Lymphoma; myeloma; brain cancer; Hodgkin's disease; non-Hodgkin's lymphoma
Chlorambucil	Chronic lymphocytic leukaemia; low grade non-Hodgkin's; Hodgkin's lymphoma; waldenstrom's macroglobulinaemia
Cisplatin	Testicular; ovarian; bladder; head and neck; lung cancer; cervical cancer; breast cancer
Melphalan	Myeloma; melanoma; ovarian cancer; sarcoma polycythemia rubra vera; advanced breast cancer
Vincristine	Leukaemia; lymphoma; myeloma; breast cancer; head and neck cancer; other cancers; paediatric solid tumours
Methotrexate	Acute lymphoblastic leukaemia; breast cancer; head and neck cancer; lung cancer; non-Hodgkin's lymphoma; osteosarcoma; other cancers

Source: Romanian Health Observatory (RHO), expert interviews



INEQUALITIES

GERMANY

Table 1. Examples of cancer medicines affected by shortages in 2018

Cancer Medicine	Indication
Capecitabine	Breast cancer; Colorectal cancer; Gastric cancer; other cancers
Carboplatin	Cervical cancer; Head and neck cancer; Ovarian cancer; Lung cancer
Etoposide phosphate	Testicular carcinoma; Lung cancer
Fludarabine	Chronic lymphocytic leukaemia; Non-Hodgkin's lymphoma; Acute myeloid leukaemia
Melphalan	Multiple myeloma, stem cell transplantation (blood cancer)
Methotrexate	Acute lymphoblastic leukaemia; Head and neck cancer; Non-Hodgkin's lymphoma; Osteosarcoma; other cancers
5-fluorouracil	Colon carcinoma; Colorectal carcinoma; other cancers

Source: Federal Institute for Drugs and Medical Devices (BfArM), 20 January 2019⁹⁹

The positive side of the story so far...

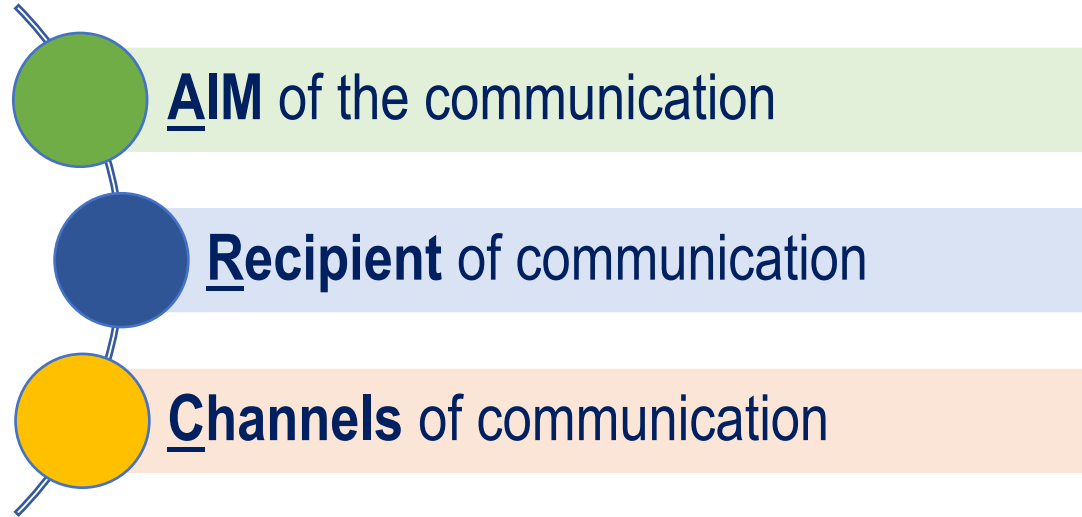


- Shortages at core of discussion (clinical, scientific and political level)
- Finally a **strategy plan** to address shortages
Moved forward from the issue of defining what shortages are
- Understanding the importance of the **global dimension of shortages**, while fully respecting the local/national competence
- Agreement on **systematic dialogue at EU and National institution level** is key,
- INCLUSIVE** dialogue
- Acknowledging the need to **lively monitor** shortages
- Multiple root causes** and as a consequence **different solutions** may apply (eg shortages due to procurement systems, shortages due to lack of raw materials, shortages due to sudden increase demand...)



ESSENTIAL TO COMMUNICATE CLEARLY THESE POINTS

CONSENSUS (?) about communication and transparency



Raise awareness/alert
Seek feed back/share solutions

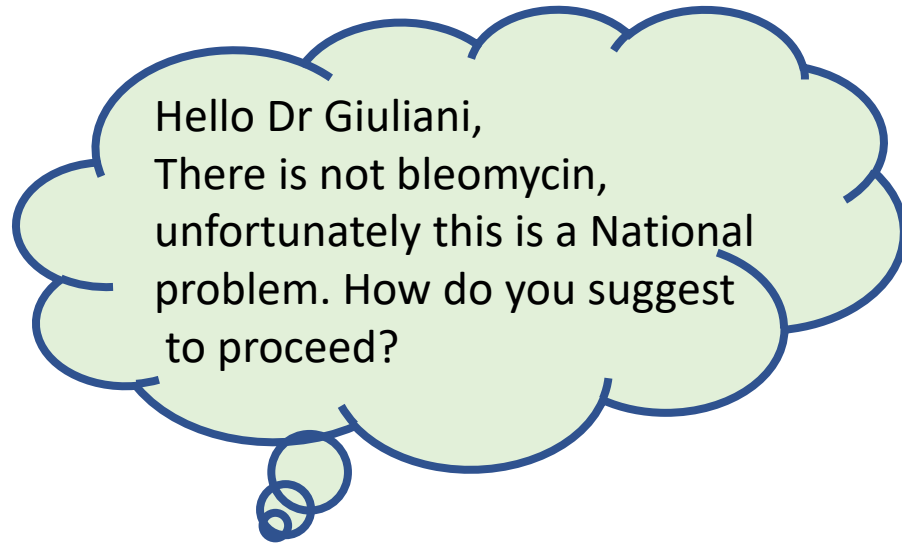
Different stakeholders/Different angles
Parallel communications? All at the same table?

E.g. learned societies websites
NCA
EU bodies (EMA)
Newsletters
Publications
Podcasts

3C: Coherent, Cohesive and Comprehensive



Sub-optimal styles of communication



FROM POLITICO PRO

Europe is running out of medicines

Common medications including antibiotics and children's painkillers are in short supply across the bloc. Here's what's being done about it.

FDA U.S. FOOD & DRUG
ADMINISTRATION

What's New Related to Drugs

February 24, 2023

- Draft Guidance: [Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment](#)
- [FDA Drug Shortages](#)
 - [Leucovorin Calcium Lyophilized Powder for Injection](#) (Updated - Currently in Shortage)
 - [Rocuronium Bromide Injection](#) (New - Currently in Shortage)
 - [Tirofiban Hydrochloride Injection](#) (New - Discontinuation)

EMA shortages catalogue

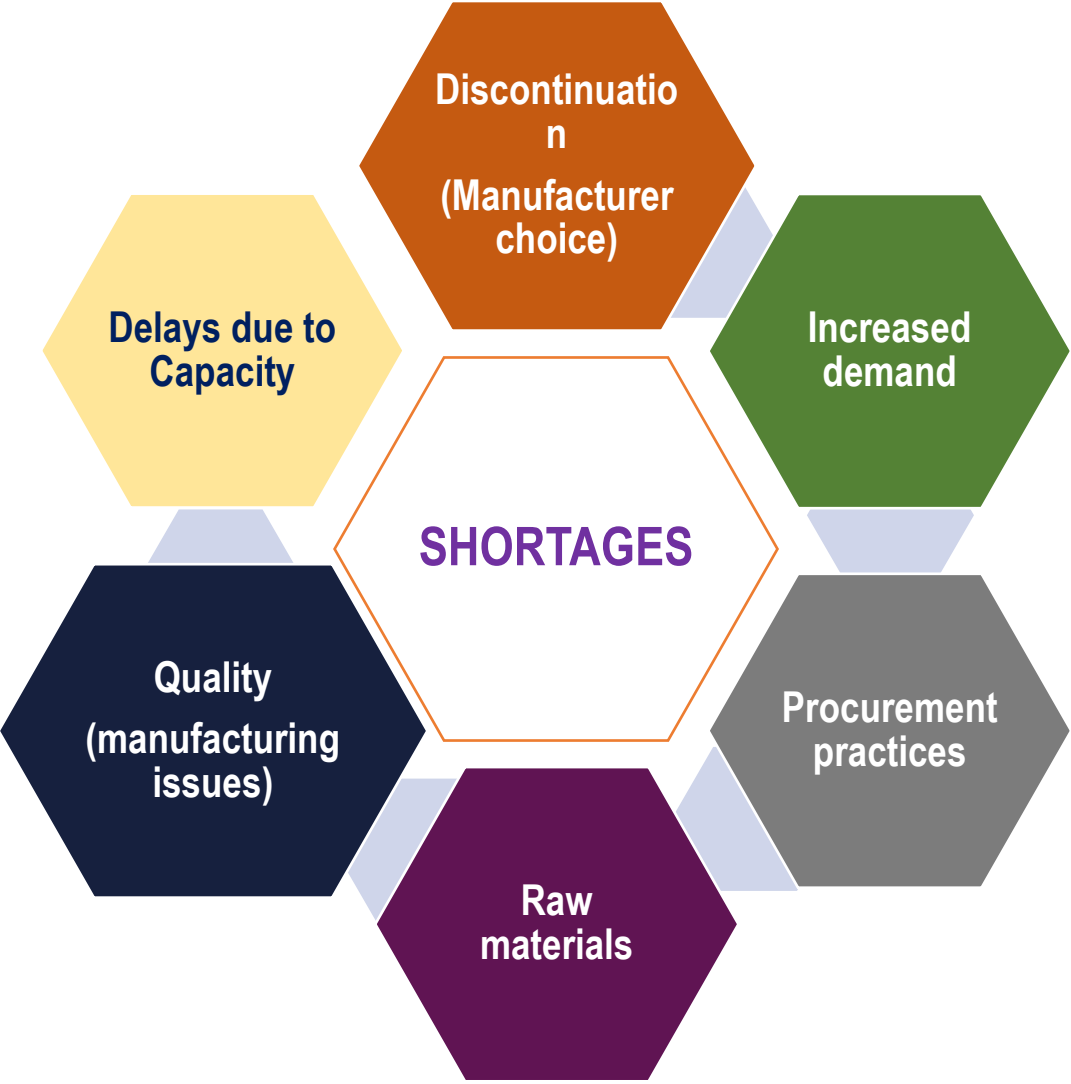
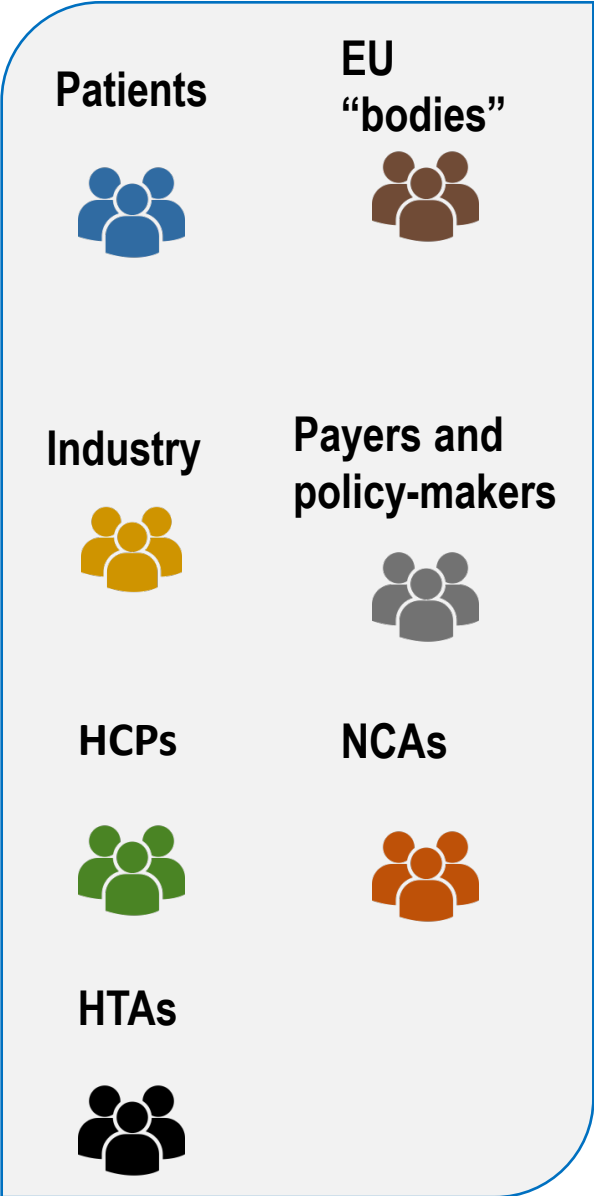
You can find information on ongoing and resolved shortages of **human medicines** that EMA has assessed at:

- [Ongoing shortages](#)
- [Resolved shortages](#)

You can **download this information in Excel table format** at:

- [Downloads: shortages](#)

TARGETED COMMUNICATION



Modalities of communication:
all comers?

Style of communication (lay
language, et cet...)

Channels

TIMING





HCPWP

Eligible healthcare professionals' organisations



Classified as internal staff & contractors by the European Medicines Agency



13 May 2022
EMA/397143/2020

Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use



Happy to discuss further

Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use

	Key recommendations	Comments
Communication and transparency	<p>Organisations should develop shortage observatories or seek links with already established shortage observatories (in collaboration with national medicine authorities and health authorities). Shortage observatories are organisations that:</p> <ul style="list-style-type: none"> – collect and analyse information from patients and healthcare professionals on shortages and the consequences on patients’ outcomes/safety/adherence to inform/raise the awareness of the health authorities so that they can take action; – collect information from healthcare professionals on changes in clinical practice that may lead to changes in demand for medicines; – collect information on early signals of potential shortages (feedback to regulator/health authority and use as trigger for mitigation practices), especially where no direct reporting mechanisms are in place. This is particularly important for local shortages; – obtain feedback from patients and healthcare professionals on risks of replacement/substitution therapies (including reducing the dose of medicines) as well as other risks (such as risk of buying medicines online from illegal channels). 	<p>These can be national, but also EU, level in order to lead to EU harmonised criteria for collection of information</p>

Risk of duplication of efforts already in place?